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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,081	02/20/2002	Rolando Wyss	205,530	2347

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EXAMINER
NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
1645	5

DATE MAILED: 09/29/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
10/081,081	Wyss et al
Examiner	**Art Unit**
Mark Navarro	1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-26 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☒ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Specification

1. The use of the trademark Protasan has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

2. Claims 9 and 14 are objected to because of the following informalities: Each of claims 9 and 14 fail to end the sentence with a period "." Appropriate correction is required.

3. Claims 4, 7, 16, 17, 20, 21, and 25 objected to because of the following informalities: Each of the recited claims is poorly worded or lacks appropriate sentence structure in its list of alternative embodiments. The article "and" or "or" should be recited as the penultimate word. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-26 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-26 are directed to compositions comprising immunoglobulins and polysaccharides, which have the same characteristics and utility as the immunoglobulins and polysaccharides found naturally and therefore does not constitute as patentable subject matter.

In the absence of the hand of man, naturally occurring products are considered non-statutory subject matter. Diamond v. Chakrabarty, 206 USPQ 193 (1980). Mere purity of naturally occurring product does not necessarily impart patentability. Ex parte Siddiqui 156 USPQ 426 (1966). However when purity results in new utility, patentability is considered. Merck Co. V. Chase Chemical Co. 273 F. Supp 68 (1967). See also American Wood v. Fiber Disintergrating Co., 90 US 566 (1974);American Fruit Growers v. Brogdex Co. 283 US 1 (1931); Funk Brothers Seed Co. V. Kalo Innoculant Co. 33 US 127 (1948). Filing of evidence of a new utility imparted by the increased purity of the claimed invention and amendment to the claims to recite the essential purity of the claimed products is suggested to obviate this rejection. For example, "An isolated composition..."

Claim Rejections - 35 USC § 112

5. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-26 provide for the use of compositions, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-26 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

6. Claim 8 contains the trademark/trade name PROTASAN. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or

trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe the chitosane and, accordingly, the identification/description is indefinite.

7. Claims 8-10, 19, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the use of the phrase "derived or derivative." Since it is unclear if the antigenic polypeptides are undergoing any kind of chemical modification as implied by the recitation of "derived or derivative." Since it is unclear how the antigenic polypeptides are to be derived as referred to in the claims, there is no way for the person of skill in the art to ascribe a discrete and identifiable definition to said phrase.

8. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is vague and indefinite in the recitation of "low molecular weight and high degree of acetylation." These are simply relative terms. For instance what is a low molecular

weight 1 kD, 10 kD, 100 kD, likewise what is a high degree of acetylation, 30%, 50%, 90%, etc.? Without a clear definition as to the relative terms of "low" and "high" one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-7 and 10-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Gombotz *et al.*

The claims are drawn to compositions comprising complexes of immunoglobulins and polysaccharides wherein the polysaccharide is not chemically cross-linked to the immunoglobulin for systemic use, wherein the polysaccharide is alginate.

Gombotz *et al* (US Patent Number 6,036,978) disclose of monoclonal antibodies encapsulated in alginate. (See abstract and claims).

In view that the antibodies disclosed by Gombotz *et al* are not cross-linked to alginate, and that the close proximity of the antibody alginate complex will undergo ionic interactions, the disclosure of Gombotz *et al* is deemed to anticipate the claimed invention.

10. Claims 1-9 and 11-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Watts *et al*.

The claims are drawn to compositions comprising complexes of immunoglobulins and polysaccharides wherein the polysaccharide is not chemically cross-linked to the immunoglobulin for systemic use, wherein the polysaccharide is chitosane.

Watts *et al* (WO 98/30207) disclose of compositions comprising a mixture of chitosan, gelatin and a therapeutic agent. Watts *et al* further sets forth the therapeutic agent to include antibodies. (See claims and page 11).

In view that the antibodies disclosed by Watts *et al* are not cross-linked to chitosane, and that the close proximity of the antibody chitosane mixture will undergo ionic interactions, the disclosure of Watts *et al* is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gombotz *et al* and Watts *et al* in view of Anderson *et al*, Griffin *et al*, Garner *et al* and Costa *et al*.

The claims are drawn to compositions comprising complexes of immunoglobulins and polysaccharides wherein the polysaccharide is not chemically cross-linked to the immunoglobulin for systemic use, wherein the antibodies react with cocaine, prothrombin, or toxins of mycotic origin.

The teachings of Gombotz *et al* and Watts *et al* are set forth above.

Neither Gombotz *et al* or Watts *et al* teach of antibodies to cocaine, prothrombin, or toxins of mycotic origin.

Anderson *et al* (US Pub No. 2003/0149254) teach of therapeutically important antibodies which specifically react with thyroid hormone, antibiotics, cocaine, cytomegalovirus, Mycobacterium, calcitonin, and human chorionic gonadotropin. (See paragraph 254).

Griffin *et al* (US Patent Number 5,679,639) teach of therapeutically important antibodies which specifically bind with prothrombin.

Garner *et al* (US Patent Number 5,429,952) teach of therapeutically important antibodies which specifically bind with aflatoxin.

Costa *et al* (Atas Soc Biol Rio De J Vol. 26, pp 15-24, 1986) teach of delipidated cells walls of Corynebacterium granulosum, which is a well known immunomodulator used for increasing the effectivity of an immune response.

Given that 1) Both Gombotz *et al* and Watts *et al* have taught of immunoglobulins in association with polysaccharides for therapeutic administration, and that 2) Anderson *et al*, Griffin *et al*, and Garner *et al* have each taught of therapeutically important antibodies reacting with cocain, prothrombin and aflatoxin, respectively, and that 3) Costa *et al* has taught of the immunomodulating effectivity being increased by the presence of delipidated cell walls of Cornybacterium granulosum, it would have been *prima facie* obvious to one of ordinary skill in

the art at the time of the invention to have incorporated the immunoglobulins taught by Anderson *et al*, Griffin *et al*, or Garner *et al* into the composition taught by Gombotz *et al* or Watts *et al*. One would have been further motivated to include a well known immunomodulater, delipidated cell wall of Cornybacterium granulosum, in view of the demonstrated increased effectiveness as taught by Costa *et al*. One would have been motivated to create such a composition in view of the teachings by Watts *et al* that the combination of chitosan and therapeutic agents (i.e., antibodies) enhances therapeutic agent uptake across mucosal surfaces.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should by faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.

Mark Navarro

Primary Examiner

September 25, 2003